REMARKS

I. Preliminary Remarks

A. Power of Attorney and Change of Correspondence Address Documents

Power of Attorney and Change of Correspondence Address documents were initially filed with the U.S. Patent and Trademark Office on April 11, 2008. For the convenience of the Office, a further copy of the documents is submitted herewith. Applicant requests that the Office update its records accordingly and address any future correspondence pertaining to this application to the undersigned.

B. Status of Claims and Explanation of Claim Amendments

Claims 2, 7, 9 and 10 are amended, claims 3-6 and 11-45 are canceled and new claims 47-59 are added herein. Support for the amended claim 2 and new claims 47-59 can be found on pages 6-9. The amendment to claim 10 corrects a typographical error. Claims 7 and 9 were amended to depend from claim 2. Accordingly, no new matter has been added..

Claims have been canceled solely to offset potential fees for new claims and not for reasons pertaining to patentability. Applicant reserves the right to pursue the subject matter of any claim (whether original, amended or canceled) in continuing applications.

II. Amendments to the Specification

The specification has been amended to include sequence identifiers for the nucleotide sequences recited in pages 16-17 of the application. No new matter has been added and no new sequence listing is necessary.

III. The rejections under 35 U.S.C. §112, second paragraph, are moot.

The Examiner rejected claims 3-4 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The rejections are moot in view of the cancellation of these claims.

IV. The rejection under 35 U.S.C. § 112, first paragraph (written description), should be withdrawn.

The Examiner rejected claims 2-7 and 9-10 under 35 U.S.C. § 112, first paragraph, for allegedly failing to be supported by the specification as filed The rejection is moot in view of the amendments made herein.

The Examiner has already indicated that polypeptides comprising the amino acid sequence of SEQ ID NO: 10 or SEQ ID NO: 11 (or encoded by the nucleotide sequences of SEQ ID NO: 8 or SEQ ID NO: 9) is supported by the specification as filed. See page 5 of the office action. Accordingly, the rejection of claims 2-7, 9 and 10 (claims 3-6 and 8 being canceled) under 35 U.S.C. § 112, first paragraph, is moot and should be withdrawn.

V. The rejection under 35 U.S.C. § 112, first paragraph (enablement), is moot.

The Examiner rejected claims 2-7 and 9-10 under 35 U.S.C. § 112, first paragraph, for allegedly failing to be supported by an enabling specification. The rejection is moot in view of the amendments made herein.

The Examiner has already indicated that a method of detecting polypeptides comprising the amino acid sequence of SEQ ID NO: 10 or SEQ ID NO: 11 (or encoded by the nucleotide sequences of SEQ ID NO: 8 or SEQ ID NO: 9) by contacting samples containing these polypeptides with antibodies is enabled by the specification as filed. See page 3 of the office action. Accordingly, the rejection of claims 2, 7, 9 and 10 (claims 3-6 and 8 being canceled) under 35 U.S.C. § 112, first paragraph, is moot and should be withdrawn.

VI. The rejection under 35 U.S.C. § 102(b) is moot.

The Examiner rejected claims 2-7, 9 and 10 under 35 U.S.C. § 102(b) as allegedly being anticipated by Anderson et al. (WO 00/52143). The rejection is moot in view of the amendments made herein.

As indicated by the Examiner on page 7 of the office action, Anderson et al. fail to explicitly disclose a polypeptide encoded by the nucleotide sequence of SEQ ID NO: 8 or 9 and antibodies that bind the polypeptide, which are required elements of claim 2. Because the cited art does disclose each element of independent claim 2, the cited art does not

anticipate any of claims 2, 7, 9 and 10. Accordingly the rejection of claims 2, 7, 9 and 10 (claims 3-6 and 8 being canceled) under 35 U.S.C. § 102(b) is moot and should be withdrawn.

VII. The rejection under 35 U.S.C. § 103(a) should be withdrawn.

The Examiner rejected claims 2-7, 9 and 10 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Samuels-Lev (Mol. Cell, 8:781-794, 2001) in view of Louis (J. Neuropathol. Exp. Neurol., 53:11-21. 1994). Applicant requests reconsideration of the rejection in view of the following remarks.

The pending claims are directed to a method of detecting ASPP1 or ASPP2 in a cell or tissue sample that comprises a nerve cell or a nerve progenitor cell.

To establish a *prima facie* case of obviousness, the Examiner must show that all the elements of the claim are taught or suggested in the prior art (M.P.E.P. § 2143.03 and Federal Register Examination Guidelines for Determining Obviousness, Section III.A.1, Fed Reg., Vol 72, No. 195, 2007), and if all claim elements are described in the art, the combination of elements must yield predictable results to render a claimed invention obvious. Further, it should be demonstrated that there was some teaching, suggestion or motivation in the prior art, or the knowledge generally available to an ordinary artisan, to combine the references, and that there was a reasonable expectation that such a combination would successfully result in the claimed invention (M.P.E.P. § 2142 and Federal Register Examination Guidelines for Determining Obviousness, Section III.G, Fed Reg., Vol 72, No. 195, 2007). The Examiner must still provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn,* 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir 2006)).

The Examiner has failed to provide a credible nexus between Samuels-Lev and Louis. Samuels-Lev reports that ASPP1 and ASPP2 stimulate the apoptotic function of p53 and further indicates that mRNA encoding ASPP1 and ASPP2 is decreased in many **breast cancers** that express wild-type p53. The Examiner relied upon Louis as teaching that not all brain cancers express mutant p53 and asserted that because of the teachings of Louis, one of

skill in the art would recognize that assays to detect p53 mutations in samples from these tumors would not be useful to determine if the tissue is in fact cancerous. The Examiner suggested that the skilled artisan would understand that **other proteins** must be used in an assay to determine whether or not tissue suspected of being cancerous is in fact cancerous.

The Examiner is reminded that there are somewhere in the neighborhood of 20,000 – 100,000 human genes (depending on whose estimates are to be believed). The notion that one would need to look to "other proteins" for evaluation of brain cancers in no way would lead a person to the proteins recited in the current claims.

The Examiner has not pointed to any particular portion of either Samuels-Lev or Louis which supports his conclusion. Samuels-Lev is silent with respect to the detection of ASPP1 and ASPP2 in a nerve cell or nerve progenitor cell. Louis does not disclose or suggest detecting ASPP1 or ASPP2 in any sample, let alone a nerve cell or nerve progenitor cell as required by the claims. Moreover, the cited art fails to support the Examiner's conclusion that detecting ASPP1 or ASPP2 in a brain tumor sample would be an improved assay for determining whether a brain tumor was a malignant tumor.

The Examiner also alleged that a person of ordinary skill in the art would be motivated to assay ASPP1 or ASPP2 in samples comprising neurons "to determine if a tumor sample suspected of being cancerous is in fact cancerous." As noted above, the cited art is entirely silent with respect to ASPP1/ASPP2 expression in tumors of neurological origin (irrespective of their p53 status). Thus, it would have been implausible, absent hindsight, for a person of ordinary skill to "be motivated" to choose to combine these two references for this purpose, i.e., to be motivated to try this assay instead of thousands of others that could have been chosen. Even if the combination were made, it would have been an exercise in curiosity only – there would have been no reasonable expectation *from the state of the art* that such a combination would successfully result in the claimed invention because there was no indication *in the cited art* of ASPP1/ASPP2 expression in tumors of neurological origin. It should be remembered that the *KSR* opinion involved a simple mechanical invention – a predictable art. As the Patent Office's reviewing court recently noted when discussing *KSR* in the chemical arts, "To the extent an art is unpredictable, as the chemical arts often are, KSR's focus on … "identified, predictable solutions" may present a difficult hurdle because

potential solutions are less likely to be genuinely predictable ...." *Eisai Co. v. Dr. Reddy's Laboratories, Ltd.* 2007-1397, -1398 (Fed. Cir. July 21, 2008) (affirming summary judgment in favor of plaintiffs on issue of non-obviousness). The present invention is in the unpredictable biotechnology arts, and this unpredictability requires that the rejection alleging obviousness be withdrawn.

In view of the foregoing, it is clear that the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, the rejections of claims 2, 7, 9 and 10 (claims 3-6 being canceled) under 35 U.S.C. § 103(a) be withdrawn.

VIII. Conclusion

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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